PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Application of: J. M. Steinke, A.P. Shepherd | § | Examiner: K. Hantis |
| Serial No.: 07/953,680 | § | Group Art Unit: 2505 |
| Filed: September 29, 1992 | § | |
| For: METHOD AND APPARATUS FOR DIRECT SPECTROPHOTOMETRIC MEASUREMENTS IN UNALTERED WHOLE BLOOD | § | Atty. Dkt.: UTSK:142/BAH |

**CERTIFICATE OF MAILING**
**37 C.F.R. § 1.8**

**I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231, on the date below:**

October 10, 1995 — David D. Bahler

**Date** **David D. Bahler**

**DECLARATION OF THOMAS SCECINA UNDER 37 C.F.R. § 1.132**

Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

I, THOMAS SCECINA, do hereby declare and state:

1. I hold electrical engineering degrees from Case Western university (B.S.E.E., 1963) and from Northeastern University (M.S.E.E., 1968).

2. I have 21 years of experience in the field of medical product development and am familiar with all of the commercially

available blood gas analyzers and co-oximeters now on the market or that have been on the market within the last 15 years.

3. From 1973 until 1995 I was employed by Corning, later called Ciba Corning, which is one of the four major international companies that manufacture and market blood gas analyzers and co-oximeters. During my employment at Corning or Ciba Corning, I worked on the development of co-oximeters such as the Corning 2500 and the Corning 270. Further details regarding my employment history are given in my resume which is attached.

4. I have read the above-identified patent application, including claims 1-36.

5. In the late 1970s, Corning carried out a research program using a team of highly qualified scientists and instrument designers who attempted to develop a method for measuring multiple hemoglobin species in unaltered whole blood. The reason for attempting to develop such a technology is that it would allow instruments to be simpler, faster, and less expensive to manufacture than co-oximeters that hemolyze each blood sample before analyzing it spectrophotometrically. Thus, the desirability of such an instrument was quite evident, and there was a long-standing need for such a design.

6. I was the division sponsor and manager of that team, and my colleagues and I were well-informed about the literature that deal with optical properties of unaltered whole blood.

7. For two reasons, we abandoned our efforts to develop an instrument for measuring multiple hemoglobin species in unaltered whole blood. First, nothing in our experiments or in the literature indicated that such measurements were feasible at the required accuracy because of the complex optical properties of unaltered whole blood. Second, our experiments indicated to us that making such measurements on unaltered whole blood might be risky and unreliable because the optical behavior of unaltered whole blood was so unpredictable from one sample to the next. Continuing the project would have involved more risk of failure and development time than we could justify.

8. After we abandoned our effort to develop an instrument for measuring multiple hemoglobin species in unaltered whole blood, our group at Corning subsequently designed co-oximeters that hemolyze each blood sample before analyzing it spectrophotometrically.

9. At the present time, four companies manufacture so-called co-oximeters that measure the total hemoglobin concentration and the relative concentrations of four hemoglobin species (Instrumentation Laboratory, Ciba Corning, Radiometer and AVL

Scientific). In every case without exception, the instruments hemolyze the blood sample first before subjecting it to spectrophotometric analysis. To the best of my knowledge, the present invention is the first and only one to succeed in making these measurements directly in unaltered whole blood without hemolysis.

10. During my employment at Ciba Corning, my colleagues and I evaluated a prototype of the above-identified invention, and we carried out experiments to quantify its accuracy and precision and to assess its performance specifically on unaltered whole blood.

11. I have reviewed performance data that demonstrate the present invention measures total hemoglobin to an accuracy of less than 0.5 g/dL and the relative concentrations of the individual species to accuracies of 1-2.5%. As an engineering manager with extensive experience in the development of clinical instruments including co-oximeters, I can attest that these accuracies are clinically and commercially acceptable.

12. As mentioned previously (see Paragraph 7 above), our development team at Ciba Corning never achieved results in unaltered whole blood that agreed closely with those in hemolyzed blood. Table IV of the present application (page 40) makes just such a comparison. To me it is quite surprising that the present

invention can make measurements in unaltered whole blood that agree so well with those in hemolyzed blood.

13. As an experienced engineering manager who worked 21 years with a major company in this field, it is my opinion that the present invention has significant advantages over prior art: (1) lower manufacturing costs due to the elimination of expensive hemolyzers; (2) a non-destructive measurement that allows the sample with intact red cells to be subjected to further hematological or other analyses; (3) a compact, rugged design; and (4) faster analyses.

14. The prior art references of which I am aware do not teach one of ordinary skill in this technology and do not teach me personally, how to make or use the invention as claimed in the above-identified patent application. In fact, the invention as claimed in this application as a whole would not have been obvious at the time the invention was made to a person having ordinary skill in this art.

15. I hereby declare that all of the statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like are punishable by fine and/or imprisonment under Section 1001 of Title 18 of the United States

Code and that such willful false statements may jeopardize the validity of the above-identified application, or any patent issuing therefrom.

7/13/95
Date

Thomas Scecina
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## R&D MANAGEMENT

## SUMMARY

Extensive experience in successfully managing development of medical diagnostic instruments and electronic systems both as department manager an as project manager. Strong track record in managing external developments of products and technology. Strengths include system design, conceptualization, problem solving, knowledge of project management techniques and broad understanding of electro-chemical and optical sensors, spectroscopy, fluidics, mechanical and electronic design, software and operator interface design.

## EXPERIENCE

**CIBA CORNING DIAGNOSTICS**, Medfield, MA — 1973 - Present
*Worldwide manufacturer of medical laboratory diagnostic instruments.*

**Manager, New Technology Assessment and Development** 1990 - Present
Apply emerging technologies to satisfy future product needs and improve development processes.

- Introduced Expert System technology enabling Technical Assistance Center to achieve goal of increased first call resolution and satisfying Product Development need to reduce immunoassay test development time.
- Directed program to study new blood analyte measurement technology with market upset potential. Negotiated research contracts with three leaders in field to assess technical feasibility.

**Sr. Manager, Systems Engineering**, 1987 - 1990
Directed department responsible for system design, performance development and FDA compliant system software validation of instruments.

- Developed extensive error analysis and error budget process resolving numerous performance problems in 270 co-oximeter.
- Instituted new test process which dramatically improved cleanliness of released software.

**Project Manager**, 1984 - 1988
Manage multidicipline teams in development and introduction of medical instruments.

- Directed team of 40 people in development and introduction of 200 Series line (three Blood Gas/Electrolyte analyzers) and 664 Electrolyte Analyzer enabling company to expand its market share lead.
- Successfully managed 664 Program including coordination between separate sites for manufacturing, marketing and product support.
- Managed OEM development by European company of gamma counter, resulting in one of company's most successful OEM products.

**Technology Planning Manager, 1981 - 1984**
Responsible for identifying future market needs through interaction with marketing personnel and customers, developing product specifications, and managing development of technology to meet product needs.

- Developed numerous research contacts for technology to support future product strategies.
- Managed research and development of a multi wavelength spectrophotometric measurement technology for 2500, company's first Co-oximeter.

**Product Development Manager, 1975 - 1981**
Built an instrument development department from small group to effective team of 25 which included capability for sensor, electronics, software, mechanical design and documentation. Proposed and directed development of two new Blood Gas instruments, #168 and #178, thrusting company into number one BG market share position.

**Supervisor, Electronic Design, 1973 - 1975**
Supervised electronic design and later directed completion of total development of #175, company's first fully automated Blood Gas analyzer. Introduced automated PC Board testing into manufacturing.

**SIERRA RESEARCH CORPORATION**, Burlington, MA 1968 - 1973
*Manufacturer of factory data collection systems.*

**Director, Systems Engineering**
Started as engineer and progressively promoted to Director. Built design department in start-up company from single engineer to effective 20 person organization. Designed and directed design of Sierra's line of factory data collection terminals, communication units, disc interface and processors.

## EDUCATION

**MSEE**, Northeastern University, Boston, MA
**BSEE**, Case Western University, Cleveland OH

## PROFESSIONAL/SERVICE ORGANIZATIONS

Professional: Institute of Electrical and Electronic Engineers
American Association of Clinical Chemists
American Association of Artificial Intelligence

Service: Medfield Lions Club, Secretary, past Treasurer, President elect